Impact of Omega-3 Fatty Acids in critically ill pediatric patients with sepsis

SHORT SYNOPSIS

Submitted in partial fulfillment of the requirement of the degree of

DOCTOR OF PHILOSOPHY

to

Manav Rachna International Institute of Research and Studies
(Deemed to be University)

by
Swati
Registration number: 19/Ph.D/120

Under the supervision of
Supervisor
Dr. Madhvi Awasthi
Assistant Professor, FAHS, MRIIRS
Co-Supervisor
Dr. Kajal Pandya Yeptho
Chief Dietician, Indraprastha Apollo Hospital

FACULTY OF ALLIED HEALTH SCIENCES
MANAV RACHNA INTERNATIONAL INSTITUTE OF RESEARCH & STUDIES
SECTOR-43, SURAJKUND –DELHI ROAD, FARIDABAD – 121001

CERTIFICATE

I hereby declare that the short synopsis "Impact of Omega-3 Fatty Acids in critically ill pediatric patients with sepsis" being submitted in partial fulfillment of the requirement for the degree of Doctor of Philosophy in Nutrition & Dietetics under Faculty of Allied Health Sciences of Manav Rachna International Institute of Research & Studies, Faridabad during the academic year 2021. It is a bona fide record of original work carried out under the supervision of Dr. Madhvi Awasthi and Dr. Kajal Pandya Yeptho and has not been submitted in full or part to any other university or institute for degree or diploma. Further, it is certified that short synopsis is plagiarism free and proof has been submitted.

Swati

Registration No. 19/Ph.D/120

(Signature of Supervisor)

Dr. Madhvi Awasthi

Assistant Professor, FAS, MRIIRS

Chairperson, DRC

(Signature of Co-Supervisor)

Co-Supervisor

Dr. Kajal Pandya Yeptho

Chief Dietician, Indraprastha Apollo Hospital

Chairperson, CDP

Dated: 4/3/2022

Recommendation

The sepsis can cause cascade of changes, leading pediatric patients to the fatality with multi-organ failure. This study will be significant in exhibiting the benefits of omega-3 Fatty acids and refrain pediatric patients from mortality. It will also show the improvement in inflammatory markers and thus will be able to enhance the recovery rate and will shorten the Intensive care unit (ICU) stay. The indirect impact of it will also be on reduction of the financial burden of patients in terms of expenses of hospital.

Abstract

Evidences from observational epidemiological studies estimates high incidences of mortality from sepsis in children. Sepsis is life threatening and occurs due to abnormal response to infection. Pathogenic invasion of the blood stream during sepsis induces inflammation due to the circulating high level of inflammatory cytokines which induces the liver to secrete of C-reactive protein. Prime focus of this study will be "Omega-3 fatty acids" (FAs) as it has "anti-inflammatory" properties.

Study will be experimental, randomized and placebo-controlled study which will include two groups of children diagnosed with sepsis. Treatment group will be provided standard nutrition with "Omega-3 FAs" supplementation and control group will receive standard nutrition without "Omega-3 FAs" supplementation. Both groups will be evaluated pre and post intervention in terms of their nutritional status, C-reactive protein and length of stay. The data will be analysed by appropriate statistical technique.

There can be two hypothesis of this study. First, there will be a significant effect of "Omega-3 FAs" in critically ill pediatric patients with sepsis. Second, there will be no significant effect of "Omega-3 FAs" in critically ill pediatric patients with sepsis.

Keywords: Sepsis, Pediatric sepsis, omega-3 FAs, nutrition, pSOFA

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Impact of Omega-3 Fatty Acids in critically ill pediatric patients with sepsis

Introduction

Sepsis is a critical condition which adversely influences pediatric populations regardless of any underlying health problems. One of the causes of mortality in children worldwide is due to sepsis- an estimate of 7.5 million deaths every year **(Mathias, 2016).** It is an infective syndrome leading to aberrations in biochemical, pathological and physiological functions. It is an important public health issue, estimating approximately 5.2% ($20 billion) of total United States hospital expense in 2011. The increasing incidences of sepsis have been reported **(Singer, 2016).**

The global epidemiological connotation of sepsis is difficult to ascertain. It is estimated that 1.2 million children and 3 million neonates diagnosed with sepsis worldwide annually. The burden of sepsis in developing countries is expected to be high **(Fleischmann-Struzek et al., 2018).**

Awareness of sepsis among general public is poor regardless of its worldwide importance. There are various indications of sepsis that make its diagnosis difficult. Many definitions and nomenclature were used for organ dysfunction, sepsis and septic shock, which lead to discordance in observed incidence and reported mortality. Initial concept that sepsis occurs due to a host's "systemic inflammatory response syndrome (SIRS)" to infection was established at a 1991 consensus conference. Since no gold standard definitions and clinical assessment criteria for sepsis exists that were clear, useful and validated. "Sepsis is a life-threatening organ dysfunction caused by a dysregulated host response to infection". "Organ dysfunction can be identified as an acute change in total Sequential Organ Failure Assessment (SOFA) scores 2 points or more consequent to the infection". The "SOFA score" supposed to be zero in patient without any pre-existing organ dysfunction. A "SOFA score" of two points or more shows approximately 10% of overall mortality risk in a patient with infection **(Singer, 2016).** An adapted and validated tool with age-adjusted parameters for critically ill pediatric patients was the "Pediatric Sequential Organ Failure Assessment (pSOFA)" score. With the use of pSOFA score, the "Sepsis-3" definition was evaluated in children, with confirmed or suspected infection **(Matics, 2017).**

An inflammatory condition in sepsis is triggered by infection. During sepsis pathogenic incursion of the blood stream causes inflammation due to the circulating high levels of "inflammatory cytokines" for instance interleukin (IL) 1b, IL-6 and tumor necrosis factor (TNF) α. Other

cytokines and Interleukin 6 stimulate the liver to secrete acute phase protein i.e., C-reactive protein (CRP), which is considered as robust "pro-inflammatory" and "anti-inflammatory" that helps in the eradication of pathogens **(Al-Biltagi et al., 2015).** The biomarkers use is promising in pediatric sepsis, though the use of biomarkers should be correlated always with clinical assessment. Two or more biomarkers used in combination may improve the sensitivity and specificity in comparison to a single biomarker use in diagnosis and prognosis of sepsis **(Lanziotti et al., 2016).** It has also been used in response to therapy once diagnosis of an infection has been confirmed.

The inflammatory response includes excessive formation of pro-inflammatory cytokines and eicosanoids which is an inflammatory mediator derived from lipid. Area of research in critical care regarding the clinical and biological effects of lipids has emerged and intervened enterally as well as parenterally during the critical illness. The prime focus of this study is "Omega-3 fatty acids" (FAs) as it has "anti-inflammatory" properties. Over the last decade, new researches have focused on the role of "Omega-3 FAs" and its impact on the formation of inflammatory cytokines and eicosanoids and their beneficial effect to the septic patients. This clinical research will be done in which "Omega-3 FAs" has been supplemented with standard nutrition and its scope will be restricted to critically ill patients with sepsis.

In pediatric patients, poor nutritional status has an adverse impact on physical and cognitive development, immune function, and clinical outcomes. In order for timely and effective nutrition intervention and care to be implemented and avoid further nutrition deterioration to improve health outcomes, it is necessary to recognise pediatric patients at nutrition risk.

Sepsis requires care in the intensive care unit (ICU) which improves outcome. Advancement in ICU care in recent times has led to decrease in sepsis related mortality **(Wischmeyer, 2018).** Constant underfeeding during the ICU stay, especially of protein, has remarkably contributed to long term quality of life (QoL) impediment and mortality. In order to advance recovery from sepsis basic metabolism should be contemplated and then targeted nutrition therapy to critically ill sepsis patient should be provided. The aim of nutritional intervention and research should highlight the understanding of nutrition requirements and its changes during the septic illness.

Continued evolvement of provision of "personalized nutritional needs", may change over the period of illness. Targeted and early intervention of nutrition therapies with probiotics, vitamin D or "omega-3 FAs" required to optimize the chances of survival of septic patients and to prosper against all the evolutionary odds.

There are several omega-3 polyunsaturated fatty acids (PUFA), the essential ones are “eicosapentaenoic acid (EPA)”, “docosahexaenoic acid (DHA)” and “alpha-linolenic acid (ALA)”. Human body is incapable to synthesize these fatty acids and therefore needs to be provided from diet. Omega-3 PUFA is the vital component of cell membranes, biotransformed to eicosanoids and other lipid derived substances that controls several biochemical processes, such as inflammation and immune responses, in the body. The omega-3 PUFA derived eicosanoids are generally considered to be anti- inflammatory **(Reimers and Ljung, 2019).**

There is an increase in the number of experimental researches on the beneficial usage of “Omega-3 FAs” in the last decade. Enriched diets with high doses of “Omega-3 FAs” reported significant benefits in treating several inflammatory diseases. “Omega-3 FAs” has the potential to attenuate inflammation. Several clinical researches have shown the impact of “Omega-3 FAs” on inflammatory biomarkers.

The aim of this research is to provide evidences on clinical efficacy and safety usage of “Omega-3 FAs” as compared to the standard care i.e., without “Omega-3 FAs”.

Literature Review

Observational epidemiological studies have shown that there is a high incidence of mortality from sepsis in children. Studies published between 1979 and 2016 and their meta-analysis reported population based sepsis incidence in newborns and children. This research yields "1270 studies, 23 of which met the inclusion criteria; 16 were from high-income countries and seven from middle-income countries". The study reported 22 severe sepsis cases and 48 cases of sepsis per 100,000 person years in children. Mortality reported between 9% to 20% in case of severe sepsis and 1% to 5% in case of sepsis. The estimate of sepsis for neonate was 2202 per 100,000 live births, with mortality ranging from 11% to 19%. Concluding from these statistics, an incidence of 1.2 million cases of sepsis in children and 3 million cases in newborns of sepsis on a global scale is reported. These figures support the hypothesis that sepsis frequently affects the newborns and children worldwide. Some figures are also available from the lower socio-income group but due to lack of standardization in definition and diagnostic criteria of sepsis these are not included in studies. Robust epidemiological surveillance to describe worldwide incidences and case fatality of sepsis in children is urgently required **(Fleischmann-Struzek et al., 2018).**

In the year 2005, children (17,542) were admitted with severe sepsis in the hospital. It was observed that there was an 81% rise in cases since 1995 and a rise of 45% cases since 2000. The years from 1995 to 2005, the severe sepsis incidences in neonates were doubled, i.e., 4.5 to 9.7 cases per 1,000 births. *Staphylococcus* species was found to be the most common infecting organisms. But the mortality rate reduced from 10.3% to 8.9%. Mortality related with *Staphylococcus aureus* is greater that mortality related with *Streptococcus pneumonia* which is reduced by 75%. Total 75,255 hospitalized children with severe sepsis were involved in United State (U.S) with an associated expense of $4.8 billion. It was concluded that "The prevalence of severe sepsis in U.S. children steadily rose, due to a significant increase in the prevalence of severe sepsis in newborns" **(Hartman et al., 2013).**

The data collected from the Children's Hospital Association between the years 2004 to 2012 with 636,842 patients with sepsis was selected from 43 hospitals. The prevalence of severe sepsis was found to be 7.7% (49,153) with a correlated mortality rate of 14.4%. It was found that "Age less than 1 year (vs age 10 to < 19) (odds ratio, 1.4), underlying cardiovascular condition (odds ratio, 1.4) and multiple organ dysfunction, conferred higher odds of mortality". The average length of

stay (LOS) in hospital was 17 days and Pediatric ICU (PICU) LOS was 7 days, and the average expense/day was $4,516 and average hospitalization expense of $77,446. It was noted that there was an increase in the rate of severe sepsis from 6.2% in 2004 to 7.7% in the year 2012 and it also showed a reduction in mortality from 18.9% to 12.0%. It was also noted that there was a negative correlation with prevalence and positive correlation with cost. Despite the prevalence increase of pediatric severe sepsis in 2004 to 2012 there was a reduction in associated mortality. Pediatric severe sepsis persists to be an important cause for hospitalization and mortality in PICU and leading towards a huge burden in healthcare expense (**Ruth et al., 2014).**

In 2007, 359 patients were included in an observational prospective cohort study. In this study the procalcitonin (PCT), leukocytes count and CRP were used to identify the absence of septic shock, severe sepsis, sepsis and infection in children. It was noted that both PCT and CRP were useful tools to identify the gravity of sepsis in patients. Though, PCT was found to be a better diagnostic marker than CRP in critically ill septic patients **(Rey et al., 2007).**

Many studies carried out for explaining the significance of nutrition in the recovery of patients. In one of the study patients of the PICU received an average of 37.7% of their estimated energy requirement (EER). The cardiac group received low energy intakes in comparison to the non cardiac patients. It was seen that out of 42 patients only 22 (52%) achieved full EER and it was more apparent in non-cardiac patients "67% versus 33%". It was also found that children who were going for cardiac surgery had a considerable drop in weight-for-age Z (WAZ) scores from the admission in PICU to discharge from hospital. Taking in to account from the time they were admitted to discharge the major hurdle in achieving EER was fluid restriction in both groups. It was noted that feeding intolerance and nil by mouth for procedures reduces energy intake to a lower extent. This study emphasizes the lack of nutrition support in critically ill PICU patients. Feed volume was the main barrier to achieve the target nutrition goal **(Rogers et al., 2003).**

One of the studies showed the effect of lipid emulsion containing fish oil on inflammatory markers and LOS. A prospective, randomized, double-blind, controlled trial was done on 32 newborns "40 $\pm$ 2.3 weeks gestational age; 10.6 days at time of surgery". These newborns were planned for open-heart surgery with "cardiopulmonary bypass", were intervened with an intravenous lipid emulsion with (experimental group) or without (placebo group) EPA and DHA. This study have shown that EPA and DHA enriched lipid emulsion decreases TNF-α level in newborns and also showed reduction in LOS with a significant time in the treatment group. Providing EPA and DHA in lipid

emulsions may enhance the inflammatory response in these critically ill newborns **(Larsen et al., 2012).**

A study conducted in 2017 revealed sepsis has a significant role in acute gastrointestinal injury (AGI). Seventy-eight patients with AGI with severe sepsis and who were on support of mechanical ventilator were randomly classified into two groups. In one group of Fish Oil (FO), long chain fatty acid FO (omega-3) 10g and soybean oil (omega-6) 50g were provided in total parenteral nutrition (TPN). On the other group, (control group) only soybean oil 50g without addition of FO was given as TPN. It was seen that the patients in FO group in comparison to the control group showed a low mortality rate and lesser CD3 T lymphocytes. The study concluded that FO has showed significant improvement in prognosis of children with sepsis and AGI **(Wang et al., 2017).**

There was a considerable improvement in platelet count, hemoglobin and total white blood cell (WBC) count and marked decrease in Erythrocyte sedimentation rate (ESR), CRP, Interleukin-6 (IL-6), and albumin level in the supplemented group with "Omega-3 FAs" as compared to non supplemented group. This supplemented group also showed shorter LOS in PICU and decrease in the mortality when compared to non supplemented group. The study showed that with the inclusion of "Omega-3 FAs" there was an improvement in inflammatory markers and number of days in PICU were decreased **(Al-Biltagi et al, 2016).**

Description of Topic

An inflammatory condition in sepsis is triggered by infection. Pathogenic incursion of the blood stream during sepsis causes inflammation due to of the circulating high levels of inflammatory cytokines which induces the liver to release C-reactive protein (CRP).

“Omega-3 FAs” is one of the essential fatty acids which are the precursor to important compounds known as eicosanoids. Ecosanoids derived from the “Omega-3 FAs” helps to reduce inflammation. “Omega-3 FAs” may lessen the concentration of “inflammatory cytokines” and its worsening effects.

This research will address the possible nutritional interventions in response to the inflammation in children suffering from sepsis.

Objectives of the study

1. To assess the nutritional status of PICU patients with sepsis age between 2years to 16years.
2. To intervene the target group with Omega 3 Fatty acids (fish oil) supplementation.
3. To evaluate the inflammatory biomarkers of PICU patients with sepsis pre and post intervention.
4. To assess the nutritional status post intervention in PICU patients.
5. To ascertain the changes in Length of stay of both the groups.

Methodology

To fulfill the objectives, the present research is divided in to the following headings:

Subjects:

A sample size of 120 subjects admitted in PICU diagnosed with sepsis will be selected for the study. Consent will be taken from the participant's guardian. These subjects will be divided in to two groups of 60 each in experimental and control group respectively.

The methodology of the study to be approved by the university's ethical committee.

Inclusion Criteria:

Age group between 2 years to16 years.

Subjects with sepsis (suspected or confirmed or as per physician diagnosis based on pSOFA score or microbiological analysis).

All septic patients who could receive nutrition in any form (oral or enteral) will be included in the study.

Exclusion Criteria:

Participant refusal

Participants with septic shock or any organ failure.

Primary or acquired immunodeficiency disease.

Immunosuppression, gastrointestinal co-morbidity, allergic to fish oil and omega-3 FAs, received omega-3 a week prior to ICU admission, critical patients with life expectancy less than 24 hours will be excluded from the study.

Sample source:

The study will be conducted in PICU of Indraprastha Apollo Hospital, New Delhi. It is one of the multi-speciality tertiary care hospitals with over 700 beds in India. Established in 1996, Indraprastha Apollo Hospital is NABH, NABL and JCI accredited.

Its 9 bed PICU has mixed population of surgical, trauma and medical patients. All who gets admitted in PICU can be included as participants in the study.

Study Area:

The present research will be carried out in New Delhi. New Delhi is an urban district and the capital of India. It is located on the bank of the Yamuna River.

Research Design:

Experimental study

Sampling Technique:

Purposive sampling

Tools:

pSOFA Score will be used to evaluate the "sepsis-3" definitions in children. It is a validated tool to diagnose sepsis.

WHO/IAP growth chart will be used to assess the nutritional status of children.

Omega-3 FA: Fish oil rich in omega 3 FAs will be used to intervene the experimental group.

Self-designed questionnaire - Participants will be evaluated on basis the following:

Demographic data: age, gender and income group.

Anthropometric data: Height, weight, BMI, birth weight.

Biochemical parameters: CRP, ESR, WBC, Procalcitonin, microbiological analysis of infection will be assessed pre and post intervention.

Diet: Consumption of Energy, protein, fat and omega 3 FAs will be calculated through 24-dietary recall assessment method.

Procedure:

As the first step management IAH will be approached for obtaining permission to conduct the study on children suffering from sepsis. Once written permission is granted from the authorities, a written consent will be taken from the participant's guardians. Screening of the participants will be performed before consent. 120 Subjects will be included as per matching the criteria of inclusion and exclusion. These subjects will be divided into two groups on randomized control trial basis. The biomarker of both the group will be taken in to account. Then the experimental group will be treated with the omega 3 FA rich fish oil with the recommended dosage **(Al-Bilgati et al., 2015).** The control group will not be intervening with any additional nutritional supplements. The changes in their parameters will be noted and analysed.

Statistical procedure:

In order to analyse the data on selected variables, appropriate statistical technique will be used.

Hypothesis of Research

1. There will be a significant effect of “Omega-3 Fatty acids” in critically ill pediatric patients with sepsis.
2. There will be no significant effect of “Omega-3 Fatty acids” in critically ill pediatric patients with sepsis.

Expected Outcome of the Research

Loss of life from sepsis in the ICU is mostly lead by the development of multiple organ dysfunctions as a result of uncontrolled inflammation. This research will help to demonstrate the beneficial effect of omega-3 FA in ameliorating the uncontrolled inflammation as well as mortality from organ dysfunction.

The amount of data available in the literature is expansive. So, this study will focus on the impact on clinical care. The potential benefit of a safe, easily-applied and effective treatment for sepsis will be emphasized under this study.

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Researcher: Ms. Swati
Registration Number: 19/Ph.D/120

Supervisor: Dr. Madhu Awasthi
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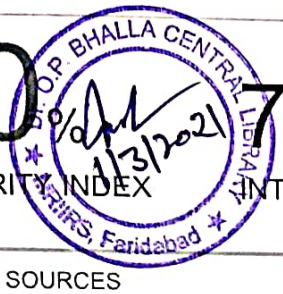

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